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L2: Entry 1 of 2

File: EPAB

Aug 20, 1998

PUB-NO: WO009835681A1
DOCUMENT-IDENTIFIER: WO 9835681 A1
TITLE: OXACARBAZEPINE FILM-COATED TABLETS

PUBN-DATE: August 20, 1998

INVENTOR-INFORMATION:

NAME

SCHLUETERMANN, BURKHARD

COUNTRY

DE

ASSIGNEE-INFORMATION:

NAME

CIBA GEIGY AG

NOVARTIS ERFINDUNGEN VERWALTUN

SCHLUETERMANN BURKHARD

COUNTRY

CH

AT

DE

APPL-NO: EP09800794

APPL-DATE: February 12, 1998

PRIORITY-DATA: CH00033197A (February 14, 1997)

INT-CL (IPC): A61K 31/55; A61K 9/28

ABSTRACT:

The invention relates to formulations, e.g. film-coated tablets containing oxacarbazepine and to processes for the production of said formulations. The film-coated tablets have a tablet core comprising a therapeutically effective dose of oxacarbazepine being in a finely ground form having a mean particle size of from 4 to 12 μ m (median value), and a hydrophilic permeable outer coating.



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61K 31/55, 9/28	A1	(11) International Publication Number: WO 98/35681 (43) International Publication Date: 20 August 1998 (20.08.98)
(21) International Application Number: PCT/EP98/00794 (22) International Filing Date: 12 February 1998 (12.02.98) (30) Priority Data: 331/97 14 February 1997 (14.02.97) CH (71) Applicant (for all designated States except AT US): NOVAR-TIS AG [CH/CH]; Schwarzwaldallee 215, CH-4058 Basel (CH). (71) Applicant (for AT only): NOVARTIS-ERFINDUNGEN VERWALTUNGSGESELLSCHAFT M.B.H. [AT/AT]; Brunner Strasse 59, A-1235 Vienna (AT). (72) Inventor; and (75) Inventor/Applicant (for US only): SCHLÜTERMANN, Burkhard [DE/DE]; Reinhard-Booz-Strasse 8, D-79249 Merzhausen (DE). (74) Agent: BECKER, Konrad; Novartis AG, Patent- und Markenabteilung, Lichtstrasse 35, CH-4002 Basel (CH).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: OXACARBAZEPINE FILM-COATED TABLETS (57) Abstract <p>The invention relates to formulations, e.g. film-coated tablets containing oxacarbazepine and to processes for the production of said formulations. The film-coated tablets have a tablet core comprising a therapeutically effective dose of oxacarbazepine being in a finely ground form having a mean particle size of from 4 to 12 μm (median value), and a hydrophilic permeable outer coating.</p>		

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L3: Entry 1 of 1

File: DWPI

Oct 28, 1999

DERWENT-ACC-NO: 1995-132460

DERWENT-WEEK: 200004

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TITLE: Colour stable 'Oxcarbazepine' tablet - has double coating contg. white pigment and low iron oxide content in outer coat

INVENTOR: BOURQUIN, J

PATENT-ASSIGNEE:

ASSIGNEE
CIBA GEIGY AG
NOVARTIS AG
CIBA GEIGY CORP

CODE
CIBA
NOVS
CIBA

PRIORITY-DATA:

1993CH-0002679

September 8, 1993

PATENT-FAMILY:

PUB-NO	PUB-DATE	LANGUAGE	PAGES	MAIN-IPC
IL 110863 A	October 28, 1999	N/A	000	A61K009/36
EP 646374 A1	April 5, 1995	G	007	A61K031/55
AU 9471571 A	March 23, 1995	N/A	000	A61K031/40
CA 2131495 A	March 9, 1995	N/A	000	A61K031/55
ZA 9406874 A	June 28, 1995	N/A	012	A61K000/00
JP 07165584 A	June 27, 1995	N/A	005	A61K031/55
US 5472714 A	December 5, 1995	N/A	004	A61K009/36
NZ 264407 A	December 21, 1995	N/A	000	A61K009/32
AU 678492 B	May 29, 1997	N/A	000	A61K031/40
US 5695782 A	December 9, 1997	N/A	004	A61K009/36
SG 44498 A1	December 19, 1997	N/A	000	A61K031/55
EP 646374 B1	April 8, 1998	G	007	A61K031/55
DE 59405627 G	May 14, 1998	N/A	000	A61K031/55
ES 2115188 T3	June 16, 1998	N/A	000	A61K031/55

DESIGNATED-STATES: AT BE CH DE DK ES FR GB GR IE IT LI LU NL PT SE AT BE CH DE DK
ES FR GB GR IE IT LI LU NL PT SE

CITED-DOCUMENTS: BE 892882; DE 2011087

APPLICATION-DATA:

PUB-NO	APPL-DESCRIPTOR	APPL-NO	APPL-NO
IL 110863A	September 5, 1994	1994IL-0110863	N/A
EP 646374A1	August 30, 1994	1994EP-0810494	N/A
AU 9471571A	August 30, 1994	1994AU-0071571	N/A
CA 2131495A	September 6, 1994	1994CA-2131495	N/A
ZA 9406874A	September 7, 1994	1994ZA-0006874	N/A
JP 07165584A	September 7, 1994	1994JP-0213510	N/A
US 5472714A	August 10, 1994	1994US-0288414	N/A
NZ 264407A	September 6, 1994	1994NZ-0264407	N/A
AU 678492B	August 30, 1994	1994AU-0071571	N/A
AU 678492B	N/A	AU 9471571	Previous Publ.
US 5695782A	August 10, 1994	1994US-0288414	Cont of
US 5695782A	August 9, 1995	1995US-0513103	N/A
US 5695782A	N/A	US 5472714	Cont of
SG 44498A1	August 30, 1994	1996SG-0001051	N/A
EP 646374B1	August 30, 1994	1994EP-0810494	N/A
DE 59405627G	August 30, 1994	1994DE-0505627	N/A
DE 59405627G	August 30, 1994	1994EP-0810494	N/A
DE 59405627G	N/A	EP 646374	Based on
ES 2115188T3	August 30, 1994	1994EP-0810494	N/A
ES 2115188T3	N/A	EP 646374	Based on

INT-CL (IPC): A61K 0/00; A61K 9/20; A61K 9/24; A61K 9/28; A61K 9/32; A61K 9/36; A61K 31/40; A61K 31/55; A61K 47/02; C07D 223/22

ABSTRACTED-PUB-NO: EP 646374A
BASIC-ABSTRACT:

Double coated oxcarbazepine (I) tablets comprise: (a) a nucleus contg. a therapeutically effective dose of (I); (b) a hydrophilic, permeable inner coating contg. white pigment and opt. other adjuvants; and (c) a hydrophilic, permeable outer coating contg. white pigment together with iron (II) oxide pigment and opt. other adjuvants. (I) is 10,11-dihydro-10-oxo-5H-dibenz[b,f]azepine-5-carboxamide ('Trileptal' (RTM)), known from DE 2011087.

USE - Tablets are used for the management of convulsions and severe pain, esp. on a long term basis.

Typical tablets contain 300mg or 600mg (I).

ADVANTAGE - The coated tablets retain a uniform colour after storage for several months, in contrast to conventional tablets, which discolour on storage at room temp.. The content of iron oxide pigment conforms with the max. daily intake of iron (5mg) permitted by the FDA.

ABSTRACTED-PUB-NO:

EP 646374B
EQUIVALENT-ABSTRACTS:

Double coated oxcarbazepine (I) tablets comprise: (a) a nucleus contg. a therapeutically effective dose of (I); (b) a hydrophilic, permeable inner coating contg. white pigment and opt. other adjuvants; and (c) a hydrophilic, permeable outer coating contg. white pigment together with iron (II) oxide pigment and opt. other adjuvants. (I) is 10,11-dihydro-10-oxo-5H-dibenz[b,f]azepine-5-carboxamide ('Trileptal' (RTM)), known from DE 2011087.

USE - Tablets are used for the management of convulsions and severe pain, esp. on a long term basis.

Typical tablets contain 300mg or 600mg (I).

ADVANTAGE - The coated tablets retain a uniform colour after storage for several months, in contrast to conventional tablets, which discolour on storage at room temp.. The content of iron oxide pigment conforms with the max. daily intake of iron (5mg) permitted by the FDA.

US 5472714A

A double-layered tablet, comprising:

- a) a tablet core containing a dosage unit of the therapeutic drug 10,11-dihydro-10-oxo-5H-dibenzo(b,f)azepine-5-carboxamide;
- b) a hydrophilic, permeable inner layer consisting of hydroxypropyl methyl cellulose and polyethylene glycol 8000 containing titanium dioxide pigments, and
- c) a hydrophilic, permeable outer layer consisting of hydroxypropyl methyl cellulose and polyethylene glycol 8000 containing titanium dioxide pigments in combination with iron(II)oxide pigments.

US 5695782A

Double coated oxcarbazepine (I) tablets comprise: (a) a nucleus contg. a therapeutically effective dose of (I); (b) a hydrophilic, permeable inner coating contg. white pigment and opt. other adjuvants; and (c) a hydrophilic, permeable outer coating contg. white pigment together with iron (II) oxide pigment and opt. other adjuvants. (I) is 10,11-dihydro-10-oxo-5H-dibenz[b,f]azepine-5-carboxamide ('Trileptal' (RTM)), known from DE 2011087.

USE - Tablets are used for the management of convulsions and severe pain, esp. on a long term basis.

Typical tablets contain 300mg or 600mg (I).

ADVANTAGE - The coated tablets retain a uniform colour after storage for several months, in contrast to conventional tablets, which discolour on storage at room temp.. The content of iron oxide pigment conforms with the max. daily intake of iron (5mg) permitted by the FDA.

CHOSEN-DRAWING: Dwg.0/0 Dwg.0/0 Dwg.0/0 Dwg.0/0

TITLE-TERMS: COLOUR STABILISED TABLET DOUBLE COATING CONTAIN WHITE PIGMENT LOW IRON OXIDE CONTENT OUTER COAT

ADDL-INDEXING-TERMS:
DI HYDRO OXO BENZ AZEPINE CARBOXAMIDE

DERWENT-CLASS: A96 B02 B07

CPI-CODES: A12-V01; B04-C02A2; B04-C03C; B05-A03A; B05-A03B; B06-D12; B12-M11; B14-C01; B14-J07;

CHEMICAL-CODES:

Chemical Indexing M2 *01*
Fragmentation Code
M431 M782 M903 M904 Q120 R038
Specfic Compounds
01966M
Registry Numbers
1966U

Chemical Indexing M2 *02*
Fragmentation Code
M431 M782 M903 M904 Q120 R038
Specfic Compounds
01508M
Registry Numbers

1508U

Chemical Indexing M1 *03*

Fragmentation Code
M431 M782 M903 M904 Q120 R038
Specific Compounds
02044M
Registry Numbers
2044U

Chemical Indexing M1 *04*

Fragmentation Code
H4 H401 H481 H5 H521 H8 M210 M211 M272 M281
M313 M321 M332 M342 M383 M391 M423 M431 M782 M903
M904 Q120 R038 V713
Specific Compounds
06563M

Chemical Indexing M2 *05*

Fragmentation Code
D013 E130 H2 H211 J5 J521 K0 L4 L432 M280
M320 M412 M431 M511 M520 M530 M540 M782 M903 M904
P411 P442 Q120 R038
Specific Compounds
21564M

Chemical Indexing M6 *06*

Fragmentation Code
M903 P411 P442 Q120 R038 R111 R120 R280 R307

UNLINKED-DERWENT-REGISTRY-NUMBERS: 1508U; 1966U ; 2044U

ENHANCED-POLYMER-INDEXING:

Polymer Index [1.1] 017 ; R06563 G3678 G3634 G3623 P0599 D01 D03 D11 D10 D23 D22 D31 D42 D50 F24 F26 F34 H0293 Polymer Index [1.2] 017 ; ND01 ; Q9999 Q7114*R ; K9712 K9676 ; K9483*R ; K9574 K9483 ; K9745*R ; Q9999 Q8037 Q7987 ; B9999 B4875 B4853 B4740 ; B9999 B3407 B3383 B3372 ; Q9999 Q7250 ; B9999 B3532 B3372 ; K9449 Polymer Index [1.3] 017 ; G2915*R D00 F20 Fe 8B Tr O* 6A ; R01966 D00 F20 Ti 4B Tr O* 6A ; A999 A102 A077 ; A999 A771 Polymer Index [1.4] 017 ; G3190 R01541 D00 F80 O* 6A Mg 2A Si 4A ; A999 A237 Polymer Index [2.1] 017 ; R00351 G1558 D01 D23 D22 D31 D42 D50 D82 F47 ; P0975 P0964 F34 D01 D10 ; P0055 ; H0000 Polymer Index [2.2] 017 ; ND01 ; Q9999 Q7114*R ; K9712 K9676 ; K9483*R ; K9574 K9483 ; K9745*R ; Q9999 Q8037 Q7987 ; B9999 B4875 B4853 B4740 ; B9999 B3407 B3383 B3372 ; Q9999 Q7250 ; B9999 B3532 B3372 ; K9449 Polymer Index [2.3] 017 ; B9999 B5094 B4977 B4740 Polymer Index [2.4] 017 ; G2915*R D00 F20 Fe 8B Tr O* 6A ; R01966 D00 F20 Ti 4B Tr O* 6A ; A999 A102 A077 ; A999 A771 Polymer Index [2.5] 017 ; G3190 R01541 D00 F80 O* 6A Mg 2A Si 4A ; A999 A237 Polymer Index [3.1] 017 ; R01852*R G3634 D01 D03 D11 D10 D23 D22 D31 D42 D50 D86 F24 F29 F26 F34 H0293 P0599 G3623 Polymer Index [3.2] 017 ; ND01 ; Q9999 Q6791 ; Q9999 Q8037 Q7987 ; B9999 B4795 B4773 B4740 ; K9745*R Polymer Index [4.1] 017 ; R06563 G3678 G3634 G3623 P0599 D01 D03 D11 D10 D23 D22 D31 D42 D50 F24 F26 F34 H0293 Polymer Index [4.2] 017 ; R07352 R06717 G3678 G3634 G3623 D01 D03 D11 D10 D23 D22 D31 D42 D50 D61 D92 F24 F34 F38 F35 Na 1A H0293 P0599 ; M9999 M2391 Polymer Index [4.3] 017 ; ND01 ; Q9999 Q6791 ; Q9999 Q8037 Q7987 ; K9745*R

SECONDARY-ACC-NO:

CPI Secondary Accession Numbers: C1995-061003

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L2: Entry 2 of 2

File: DWPI

Mar 13, 2000

DERWENT-ACC-NO: 1998-456864

DERWENT-WEEK: 200032

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TITLE: Tablets containing finely ground oxacarbazepine - for oral treatment of convulsions provide enhanced bioavailability and may be film coated

INVENTOR: SCHLUETERMANN, B

PATENT-ASSIGNEE:

ASSIGNEE

CODE

NOVARTIS AG

NOVS

NOVARTIS-ERFINDUNGEN VERW GES MBH

NOVS

PRIORITY-DATA:

1997CH-0000331

February 14, 1997

PATENT-FAMILY:

PUB-NO	PUB-DATE	LANGUAGE	PAGES	MAIN-IPC
SK 9901098 A3	March 13, 2000	N/A	000	A61K031/55
WO 9835681 A1	August 20, 1998	E	021	A61K031/55
ZA 9801205 A	October 28, 1998	N/A	017	A61K000/00
AU 9866222 A	September 8, 1998	N/A	000	A61K031/55
NO 9903919 A	August 13, 1999	N/A	000	A61K031/55
KR 98071337 A	October 26, 1998	N/A	000	A61K009/28
CZ 9902879 A3	November 17, 1999	N/A	000	A61K031/55
EP 966287 A1	December 29, 1999	E	000	A61K031/55
BR 9807368 A	March 14, 2000	N/A	000	A61K031/55
CN 1247471 A	March 15, 2000	N/A	000	A61K031/55

DESIGNATED-STATES: AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB
GE GH GM GW HU ID IL IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX
NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG US UZ VN YU ZW AT BE CH DE
DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW NL OA PT SD SE SZ UG ZW AT BE CH
DE DK ES FI FR GB GR IE IT LI LU MC NL PT RO SE SI

APPLICATION-DATA:

PUB-NO	APPL-DESCRIPTOR	APPL-NO	APPL-NO
SK 9901098A3	February 12, 1998	1998WO-EP00794	N/A
SK 9901098A3	February 12, 1998	1999SK-0001098	N/A
WO 9835681A1	February 12, 1998	1998WO-EP00794	N/A
ZA 9801205A	February 13, 1998	1998ZA-0001205	N/A
AU 9866222A	February 12, 1998	1998AU-0066222	N/A
AU 9866222A	N/A	WO 9835681	Based on
NO 9903919A	February 12, 1998	1998WO-EP00794	N/A
NO 9903919A	August 13, 1999	1999NO-0003919	N/A
KR 98071337A	February 13, 1998	1998KR-0004327	N/A
CZ 9902879A3	February 12, 1998	1998WO-EP00794	N/A
CZ 9902879A3	February 12, 1998	1999CZ-0002879	N/A
CZ 9902879A3	N/A	WO 9835681	Based on
EP 966287A1	February 12, 1998	1998EP-0908091	N/A
EP 966287A1	February 12, 1998	1998WO-EP00794	N/A
EP 966287A1	N/A	WO 9835681	Based on
BR 9807368A	February 12, 1998	1998BR-0007368	N/A
BR 9807368A	February 12, 1998	1998WO-EP00794	N/A
BR 9807368A	N/A	WO 9835681	Based on
CN 1247471A	February 12, 1998	1998CN-0802497	N/A

INT-CL (IPC): A61K 0/00; A61K 9/28; A61K 31/55; C07D 0/00

ABSTRACTED-PUB-NO: WO 9835681A
BASIC-ABSTRACT:

Formulation (I) comprises oxacarbazepine (II) with a median particle size of 1-12 μ m, preferably 4-12 μ m, and more preferably 4-10 μ m, with a maximum residue on a 40 μ m sieve of at most 5%, e.g. 2%. Also claimed is (II) in the finely ground form specified above and film-coated tablets composed of it.

USE - (II) Is the agent of choice for the treatment of convulsions.

ADVANTAGE - (I) Provides a form of (II) which can be easily processed into dosage forms and which may increase bioavailability and patient compliance. Optionally tablets have hydrophilic permeable coatings.

CHOSEN-DRAWING: Dwg.0/0

TITLE-TERMS: TABLET CONTAIN FINE GROUND ORAL TREAT CONVULSANT ENHANCE FILM COATING

DERWENT-CLASS: B02

CPI-CODES: B06-D12; B14-J07;

CHEMICAL-CODES:

Chemical Indexing M2 *01*

Fragmentation Code

D013 E130 H2 H211 J5 J521 K0 L4 L432 M280

M320 M412 M511 M520 M530 M540 M781 M903 M904 P442

R032 R036 R038

Specific Compounds

21564K 21564T 21564U

SECONDARY-ACC-NO:

CPI Secondary Accession Numbers: C1998-138107

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	Derwent World Patents Index	
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Term:	trileptal	▲
		▼

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JPAB,EPAB,DWPI,TDBD	trileptal	1	<u>L3</u>
JPAB,EPAB,DWPI,TDBD	oxacarbazepine	2	<u>L2</u>
USPT	oxacarbazepine	0	<u>L1</u>